UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/769,686 | 01/30/2004 | Lijun Xia | 5920.002 | 9134 |

30589 7590 08/01/2006

DUNLAP, CODDING & ROGERS P.C.
PO BOX 16370
OKLAHOMA CITY, OK 73113

| EXAMINER | |
|---|---|
| BELYAVSKYI, MICHAIL A | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1644 | |

DATE MAILED: 08/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/769,686 | XIA ET AL. | |
| | Examiner | Art Unit | |
| | Michail A. Belyavskyi | 1644 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *07 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *14-19,22-41,55-60 and 63-73* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-19,22-41,55-60 and 63-73* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

1. Applicant's amendment, filed 06/07/06 is acknowledged.

Claims 14-19, 22-41, 55-60 and 63-73 are pending.

Applicant's election with traverse of Group II, claims 14-19,22-32 and 55-60 in the reply filed on 06/07/06 is acknowledged. The traversal is on the ground(s) that as amended , claims of Group II and IV are not patentably distinct .

Upon consideration of applicant's arguments, filed 06/07/06 the prior art search has been extended to include amended claims of group IV.

*Claims 14-19, 22-41, 55-60 and 63-73 drawn to a composition of treated HSC and a blood product comprising said HSC are under consideration in the instant application.*

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention *to which the claims are directed.*

3 . The following is a quotation of the second paragraph of 35 U.S.C. 112.
*The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.*

4. Claims 14-19, 22-41, 55-60 and 63-73 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claims 14 –19, 22-32, 55-60 are indefinite and ambiguous in the recitation of "treated HSCs". The characteristics and metes and bounds of "treated HSCs " are unclear and indefinite. For example on page 16, of the instant specification, it is disclosed that HSCs are treated with CD34-binding antibody. On page 17 of the instant specification, it is disclosed that HSCs are treated *in vitro* with $\alpha$ 1,3 fucosyltransferase in the presence of a fucose donor.

It is suggested that Applicant amended said claims to recite " fucosylated HSCs, wherein said fucosylated HSCs are produced by treating HSCs *in vitro* with an α 1,3 fucosyltransferase in the presence of a fucose donor" for clarity and consistency with the disclosure of the Specification.

6. Claims 33-41 and 63-73 are indefinite and ambiguous in the recitation of "providing a quantity of HSCs". The characteristics and metes and bounds of "quantity of HSCs " are unclear indefinite and not disclosed in the Specification.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 14-19, 22-41, 55-60 and 63-73 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for composition comprising fucosylated HSCs, wherein said fucosylated HSCs are produced by treating HSCs *in vitro* with an α 1,3 fucosyltransferase in the presence of a fucose donor and wherein said HSCs have enhanced binding to P-selectin or E-selectin, does not reasonably provide enablement for a composition comprising any treated HSCs. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification does not enable one of skill in the art to practice the invention as claimed without undue experimentation.

(A) The claims as written encompass the genus of treated HSCs with enhanced binding to P-selectin or E-selectin.

Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, the limited working examples, the unpredictability in the art and the amount of experimentation required to enable one of skill in the art to practice the claimed invention.

Applicant discloses only a composition comprising fucosylated HSCs, wherein said fucosylated HSCs are produced by treating HSCs *in vitro* with an α 1,3 fucosyltransferase in the presence of a fucose donor and wherein said HSCs have enhanced binding to P-selectin or E-selectin ( see entire Specification, page 27-28 in particular).

Applicant has not taught how to make or use any "treated" HSCs, wherein said treated HSCs would have an enhanced binding to P-selectin or E-selectin The structural and functional characteristics of said treated HSCs are not defined in the claim.

Since the instant fact pattern fails to indicate that representative number of structurally related treated HSCs is disclosed, the artisan would not know the identity of a reasonable number of representative treated HSCs falling within the scope of the instant claims and consequently would not know how to make them. An assay for *finding* a product is not equivalent to a positive recitation of *how to make* a product.

The specification does not provide sufficient teaching as to how it can be assessed that any treatment of HSCc would result in obtaining HSCs with enhanced binding to P-selectin or E-selectin. Moreover, Hidalgo et al., ( Blood, 2005, Vol.105, pages 567-575) and Katayama et al., ( Blood, 2003,Vol.102, pages 2060-2067) each teaches that only treatment of neonatal HSCs with $\alpha$ 1,3 fucosyltransferase in the presence of a fucose donor would result in fucosylated HSC with enhanced binding to P-selectin or E-selectin.

Thus, Applicant has not provided sufficient guidance to enable one skill in the art to make and use a claimed composition comprising any treated HSCs in manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement. *In re Fisher*, 166 USPQ 18(CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute.

In view of the quantity of experimentation necessary, the unpredictability of the art, the lack of sufficient guidance in the specification, the limited working examples, and the limited amount of direction provided given the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

*(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.*

10. Claims 14 –19, 22-32, 55-60 are rejected under 35 U.S.C. 102(b) as being anticipated by Frenette et al (IDS).

It is noted that during patent examination, the pending claims must be "given the broadest reasonable interpretation consistent with the specification." See MPEP 2100. Claim 14 broadly recited "treated HSCs". Thus, when claim 14 is given its broadest reasonable interpretation , it can read on any treated HSCs.

Frenette et al., teach a composition comprising treated HSC, comprising $CD34^+$ HSCs ( see entire document, Material and Method in particular).

Claims 15-19 and 23-27 and 56-60 are included because the claimed functional limitation would be inherent properties of the referenced cell composition. Both the referenced and the instant claims recited a composition of "treated" HScs. If the prior art structure is capable of performing the intended use, then it meets the claim. When a claim recites using an old composition or structure (e.g. high affinity anti-MIF antibody) and the use is directed to a result or property of that composition or structure then the claim is anticipated. See MPEP 2112.02. Also, see Bristol-Myers Squibb Co. v. Ben Venue Laboratories, Inc. 58 USPQ2d 1508 (CA FC 2001); Ex parte Novitski 26 USPQ 1389 (BPAI 1993); Mehl/Biophile International Corp. V. Milgraum, 52 USPQ2d 1303 (Fed. Cir. 1999); Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999). Since the office does not have a laboratory to test the reference treated HSCs it is applicant's burden to show that the reference treated HSCs do not have the same functional properties as recited in the claims. See *In re Best*, 195 USPQ 430, 433 (CCPA 1977); *In re Marosi*, 218 USPQ 289, 292-293 (Fed. Cir. 1983); *In re Fitzgerald et al.*, 205 USPQ 594 (CCPA 1980).

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskyi whose telephone number is 571/272-0840. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571/272-0841.

The fax number for the organization where this application or proceeding is assigned is 571/273-8300

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MICHAIL BELYAVSKYI, PH.D.
PATENT EXAMINER

7/28/06